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MARSHALL, GERSTEIN & BORUN LLP
233 SOUTH WACKER DRIVE
6300 SEARS TOWER
CHICAGO, IL 60606-6357

EXAMINER	
FITZPATRICK, ATIBA O	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,107	Applicant(s) LE BRAS ET AL.	
	Examiner ATIBA O. FITZPATRICK	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/26/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 13 is objected to because of the following informalities: The claim mentions a variable that is either written xl0 or x10, but none of these variables is present in the equation. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The independent claims discuss the determination of a composite index, but do not discuss the purpose or usefulness of this composite index. The claimed limitations are akin to solely mathematical manipulation with no purpose, which is not statutory.

Claims 1-18 and 25 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent and recent Federal Circuit decisions indicate that a statutory "process" under 35 U.S.C. 101 must (1) be tied to another statutory category (such as a particular apparatus), or (2) transform underlying subject matter (such as an article or material) to a different state or thing. While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform underlying subject matter nor positively tie to another statutory category that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. For example, the body of the claims should state that the steps are carried out by a processor. At the least, the significant step of determining the composite index in claim 1 is not required to be carried out on a machine. A physical or chemical transformation is clearly not being claimed. While modification of data is being claimed, a depiction of the modified data is not being claimed. This assessment is true for all independent claims and the dependent claims do not remedy these deficiencies.

Claim 24 includes the limitations "Computer program for processing radiographic images", but these limitations do not fall in a statutory category. Claim 25 includes the limitation "Computer program product comprising program code means stored on a support readable by a computer", but one is not required to interpret these limitations such that they fall in a statutory category. A "computer program product" does not require the interpretation that a machine or manufacture is used for storing the program. One cannot know whether "a support" is a machine, manufacture, or something else.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The dependent claims do not remedy these deficiencies.

Claim 16 uses the phrase “and/or”. Note that for this phrase to be enabled, the alternatives must be included in at least 3 separate embodiments in the specification. Several separate embodiments must exist wherein only one of the alternatives is being used in each embodiment respectively and one embodiment must exist wherein all alternatives are being used together.

Independent claims 1, 19, and 24 include the limitations “referred to a surface area unit”, but when read in the context of the claims, these limitations make no sense. What is referred to a surface area unit? How is the item referred to a surface area unit?

Why is the item referred to a surface area unit? The specification merely duplicates the recitation present in the claims and does not enable one to make or use the invention in this regard. The dependent claims do not remedy these deficiencies

Claim 22 includes the limitations “a detector comprising a line of detection cells perpendicular to the axis of translation”, but there is no enablement for the detection cells being perpendicular to the axis of translation. Fig 1 shows the detector plane is parallel to the axis of translation. For the detection cells to be perpendicular to the axis of translation, it must be true that the detection plane can be extended such that the axis can intersect the plane, but this is not possible.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-18, and 25 are indefinite since independent claim 1 includes only steps ‘d’ and ‘e’ without inclusion of preceding steps a-c. Clearly, the steps presented in claim 1 are subsequent steps in a process, but one cannot know what is entailed in the preceding steps. The listed dependent claims do not remedy these deficiencies.

Claims 1-3, 9-13, 15-20, and 23-25 are indefinite since the independent claims refer to first incidence and first image but do not state the existence of subsequent incidences or images. The listed dependent claims do not remedy these deficiencies.

Independent claims 1, 19, and 24 include the limitations “referred to a surface area unit”, but when read in the context of the claims, these limitations make no sense. What is referred to a surface area unit? How is the item referred to a surface area unit? Why is the item referred to a surface area unit? The dependent claims do not remedy these deficiencies.

The independent claims include the limitations “on the one hand” and “on the other hand”. One cannot know, when “the one hand" is and when “the other hand is”. That is, if there is a condition that governs when either the “first digitized radiological data” or the “three-dimensional generic model” is used, one cannot know what this is. One cannot know if this condition is related to time or some other value. Claim 12 includes similar limitations, and thus similar deficiencies. The dependent claims do not remedy these deficiencies.

Steps "b" of claim 2, “b’" of claim 5, and the analogous limitations present in claim 20 are unclear and need to be rewritten for the sake of clarity. For instance, the excerpt “in the first incidence, each anatomical part comprising said osseous body and transmitted by each of the scanned parts, and delivering, from the detection means , signals corresponding to the radiation transmitted” taken from claim 2 makes no sense. In rewriting the instant limitations, consideration should be given to proper grammar and the proper use of punctuations.

Claims 9 and 15 recite the limitation "the three-dimension reference system". Claim 9 recites the limitation "the geometric position". Claim 11 recites the limitation “the match”. Claim 13 recites the limitation “the value of the quadratic sum”. There is

insufficient antecedent basis for these limitations in the claims. Claim 17 recites the limitations "the angle", “the mass”, “the section”. Claim 18 recites the limitation "the specific parameters", “the bone geometry”, "the physical parameters”, and “the angle”.

Claim 12 states that some markers are called "non-stereo-corresponding control markers". Note that the office is not concerned with what an item is called. The office is only concerned with what an item is and how it functions and how it is significant to the claimed invention. This is an inappropriate use of quotations in the claim.

Claim 23 states equations “fi”, but does not define these equations. Furthermore, claim 23 states “R in R”, but does not state what this means.

Claim 22 includes the limitations “a detector comprising a line of detection cells perpendicular to the axis of translation”, but there it is not clear how the detection cells are perpendicular to the axis of translation. Fig 1 shows the detector plane is parallel to the axis of translation. For the detection cells to be perpendicular to the axis of translation, it must be true that the detection plane can be extended such that the axis can intersect the plane, but this is not possible.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-10 and 15- 25 rejected under 35 U.S.C. 102(a) as being anticipated by WO 0238045 (Charles).

Arguments made in rejecting claims 1, 24, and 25 are analogous to arguments for rejecting claim 19. Charles also teaches computer program stored on support **(See arguments made for rejecting claim 19 Charles: paras 75, 86, 95, 159; Fig. 10)**.

Arguments made in rejecting claims 2-5, and 8 are analogous to arguments for rejecting claim 19-21. Note that the citations offered refer to multiple images pertaining to multiple angles of incidence.

As per claim 6, Charles teaches Method according to Claim 5, in which the first and second radiological data are obtained respectively in the first incidence and second incidence, by two consecutive scans of said anatomical part **(Charles: paras 17-22: particularly 17; Fig. 1)**.

As per claim 7, Charles teaches Method according to Claim 5, in which the first and second radiological data are obtained by simultaneous scanning, in the first incidence and second incidence, of said anatomical part **(Charles: Fig. 1: note that the fan-beam projection results in a plurality of data with each pertaining to a different angle of incidence of the projected light. This fan-beam projection onto the detector array and image forming of the plurality of data is performed**

simultaneously).

As per claim 9, Charles teaches Method according to claim 1, in which step (e) comprises the following subsidiary steps consisting in:

(e1) identifying, on at least the first image, predetermined markers corresponding to said osseous body, (e2) determining in the three-dimension reference system, and by virtue of first means of reconstruction, the geometric position of each marker identified in step (e1) **(Charles: Figs. 9a, 9d; Fig. 6c: 664-666; Fig. 7: 702-706; Fig. 3: 370: "bone positions, cross sections"; para 133)**, and

(e3) determining, by virtue of second means of reconstruction, the three-dimensional shape of an actual model representing said osseous body, by deformation of a predetermined generic model while at the same time keeping markers of this generic model in coincidence, during deformation, with the markers reconstructed by the first means of reconstruction **(Charles: Fig 7: particularly 714-716; paras 143-146: "It is anticipated that a conebeam reconstruction with from three to seven projections is adequate to produce a pseudo 3-D geometry that is mechanically equivalent to a measured hip. FIG. 9D is a sequence of seven images depicting a cone-beam reconstruction used to construct a 3-D model according to steps of the method in FIG. 7". The measured hip can be understood to be the generic model and the computed model can be understood to be the actual model or vice versa. Also, Fig. 8: 810; paras 148-150)**.

As per claim 10, Charles teaches Method according to Claim 9, in which the generic model is deformed in such a way that the actual model follows a shape which is as close as possible to an isometry of the generic model **(Charles: See arguments made for rejecting claim 9)**.

As per claim 15, Charles teaches Method according to claim 1, comprising a step (h) which consists in performing a radiographic calibration of the three-dimensional environment of said osseous body by defining the three-dimensional reference system in which are expressed the coordinates of each X-ray source and of the detection means for each incidence **(Charles: para 16: "calibrating bone properties"; <u>para 61</u>; Fig. 1; para 47-50; Fig. 3: 310-320; Fig. 4; paras 80-81, 96-113)**.

As per claim 16, Charles teaches Method according to claim 1, in which, during the operation (e), contour lines corresponding to limits of said osseous body and/or to lines of greater grey level density inside these limits are plotted on each image **(Charles: Fig. 9a, 9d. The contours are the edges of the bones)**.

As per claim 17, Charles teaches Method according to claim 1, in which the composite index is a parameter chosen from among
a specific parameter of the bone geometry, chosen from among the angle, length, surface and volume of an osseous part **(Charles Fig. 6c: 664 and 670; para 118:**

“bone orientation… long axis of the bone”; Fig. 9d),

a physical parameter chosen from the bone mineral density and

the mass of an osseous part **(Charles: Fig. 3: 360; Fig. 4; Fig. 6: 640, 668)**,

a mechanical parameter chosen from the section modulus and

moments of inertia of an osseous part **(Charles: Fig. 3: 390; Fig. 6: 670; Fig. 7; Fig. 8: 806; Fig. 9c; para 91; para 118: “moments of inertia”)**, and

a chemical parameter chosen from the water composition, fat composition and bone composition of an anatomical part comprising said osseous body **(Charles: Fig. 6b; para 87: “if no bone is available”; para 118: “determine how much of the soft tissue mass is lean and how much is fat”; para 125: “determining soft tissue decomposition… composition of soft tissue”)**,

or any combination of at least two of the preceding parameters **(Charles: See forgoing arguments)**.

Arguments made in rejecting claim 18 are analogous to arguments for rejecting claim 17.

As per claim 19, Charles teaches Device for radiographic imaging, comprising:

calculation means designed to calculate first digitized radiological data from signals delivered by means of detection of X-rays and corresponding to pixels of a first image of an anatomical part comprising an osseous body and scanned **(Charles: abstract: pages 3-5: “dual-energy x-ray absorptiometry apparatus…first image data having**

pixels indicating bone mineral density"; para 17; Fig. 1: 160; Fig. 3: 350-398), in a first incidence **(Charles: abstract: pages 3-5: "first angle")**, with a beam of X-rays having an energy spectrum distributed about at least two energies **(Charles: abstract: pages 3-5: "dual energy")**, these first data comprising, for each pixel, coordinates of the pixel in the first image and absorptiometry values designed to calculate the bone mineral density of the osseous body **(Charles: abstract: pages 3-5: "absorptiometry…first image data having pixels indicating bone mineral density" Note that pixels are known to represent coordinate information. At the very least, a pixel represents a coordinate in image space. An osseous body is known to contain bones)**, referred to a surface area unit **(Charles: para 16 "first conic-surface function"; para 101: "The thicknesses**
occur between five top surface"; Fig. 2a: "area detector"; para 58: "energy per unit area"; para 87 "mass per unit area"; para 134: "bone area is computed"; Fig. 4b), and storage means for storing at least one three-dimensional generic model of said osseous body **(Charles: Fig. 10; Fig. 3: 350-370, <u>390</u>-398; Fig. 8: 806-810. Note that the data must be stored to be used)**,

characterized in that the calculation means are also designed to determine the value of a composite index using, on the one hand, first digitized radiological data, and, on the other hand, at least one three-dimensional generic model of said osseous body, stored in the storage means **(Charles: abstract: pages 3-5: "for computing principal moments of intertia and strength moduli of individual bone, plus risk of injury and**

changes in risk of injury to a patient"; Fig. 3: 350-370, 390-398; Fig. 8: 806-810; para 91: "three-dimensional (3-D) model"; para 75, 77, 90-94; Fig. 7).

As per claim 20, Charles teaches Device according to Claim 19, comprising in addition: radiation-generating means designed to generate, in at least a first incidence, at least one beam of X-rays having an energy spectrum distributed about at least two energies and to scan at least one anatomical part comprising said osseous body **(Charles: See arguments made for rejecting claim 19. Figs 1-3)**,
means of detection designed to detect the energy of the radiation corresponding to the X-rays scanning, in the first incidence, each anatomical part comprising said osseous body and transmitted by each of the scanned parts, and to deliver, from the detection means, signals corresponding to the radiation transmitted **(Charles: See arguments made for rejecting claim 19. See arguments made for rejecting claim 19. Figs 1-3; para 60)**,
means for digitizing and recording the signals delivered by the detection means and corresponding at least to the first incidence, in order to constitute the first radiological data **(Charles: See arguments made for rejecting claim 19. Figs 1-3)**.

As per claim 21, Charles teaches Device according to Claim 20, in which:
the radiation-generating means are also designed to generate, in a second incidence not parallel to the first incidence, a beam of X-rays having an energy spectrum distributed about at least one energy, and to scan at least one anatomical part

comprising said osseous body **(Charles: see arguments made for rejecting claims 19 and 20. abstract: pages 3-5: There are three images and each one is associated with light at different angles of incidence. This is a dual-energy apparatus)**,

the means of detection are also designed to detect the energy of the radiation corresponding to the X-rays scanning, in the second incidence, each anatomical part comprising said osseous body and transmitted by each of the scanned parts, and to deliver signals corresponding to the radiation transmitted **(Charles: See arguments made for rejecting claim 19. abstract; Figs 1-3)**,

the means of digitization and recording are also designed to digitize and record the signals delivered by the detection means and corresponding to the second incidence, in order to constitute second radiological data **(Charles: See arguments made for rejecting claim 19. abstract; Figs 1-3)**.

As per claim 22, Charles teaches Device according to Claim 20, in which:

the radiation-generating means consist of a single X-ray radiation source generating alternately two X-ray beams, each corresponding to a different energy spectrum, this radiation source being movable, relative to said osseous body, in a plane comprising the first incidence and second incidence and also along an axis of translation perpendicular to this plane **(Charles: See arguments made for claims 19 and 20. Fig. 1: Fig. 1a: "multiple-projection, dual-energy x-ray absorptiometry": Fig. 1b: "different projection angle"; paras 47-49, 52-55: "In a dual-energy system, the**

power supply also drives the x-ray tube at a different voltage V2, which causes a different distribution of x-ray energies (frequencies) with a different cutoff energy (at a second cutoff fiequency vc2) and a different peak energy (at a second peak frequency vp2)". The same power supply cannot drive the x-ray tube at different voltages simultaneously; para 83: "the next energy beam is one of the two or more photon energies"; Fig. 3: 328), and in which the detection means consist of a detector comprising a line of detection cells perpendicular to the axis of translation, the radiation source and the detector being aligned on a source-detector axis parallel to the plane comprising the first incidence and second incidence **(Charles: See arguments made for claims 19 and 20. Fig. 1-2. From view figure 1, it is apparent that the radiation source and the detector are aligned on a source-detector axis parallel to the plane comprising the first incidence and second incidence; para 72)**.

As per claim 23, Charles teaches Device according to Claim 19, in which the calculation means are designed to plot contours or points of the surface of said osseous body on an image of form: Im(x, y) = **[Refer to the image file wrapper for amended claim 23 filed 6/20/05]** where the ai are real coefficients, the fi are functions of R in R, the Si(x,y) are the absorptiometry values for each pixel (x,y) of said image obtained with a radiation whose energy distribution corresponds to a spectrum i **(Charles: Fig. 4,6-9; para 111; paras 16-19. This can be understood to mean that the pixel values are points that are rendered (plotted) in the bone-surface containing image according to the**

equation. This can also be interpreted to mean that the bone-surface containing image is created according to the equation, and points pertaining to the bone-surface are plotted. The citations support both interpretations. In considering the equation, not that ai can be assumed to be any value including zero and 1. "i" need not range past one; however the reference refers to multiple individual images pertaining to multiple angles of incidence. "fi" can be arbitrary. Absorptiometry values pertain to x-ray attenuation in tissues. Note that the coordinates (x,y) can be understood to pertain to the pixel locations in the detector array).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-14, 16, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0238045 (Charles) as applied to claims 1 and 19 above, and further in view of "3D Reconstruction Method From Biplanar Radioraphy Using Non-stereocorresponding Points and Elastic Deformable Meshes", Mitton et al., Medical and Biological Engineering and Computing, 2000, Vol. 38. (Mitton).

As per claim 9, Charles teaches Method according to claim 1, in which step (e) comprises the following subsidiary steps consisting in:

(e1) identifying, on at least the first image, predetermined markers corresponding to said osseous body, (e2) determining in the three-dimension reference system, and by virtue of first means of reconstruction, the geometric position of each marker identified in step (e1) **(Charles: Figs. 9a, 9d; Fig. 6c: 664-666; Fig. 7: 702-706; Fig. 3: 370: "bone positions, cross sections"; para 133)**, and

(e3) determining, by virtue of second means of reconstruction, the three-dimensional shape of an actual model representing said osseous body, by deformation of a predetermined generic model while at the same time keeping markers of this generic model in coincidence, during deformation, with the markers reconstructed by the first means of reconstruction **(Charles: Fig 7: particularly 714-716; paras 143-146: "It is anticipated that a conebeam reconstruction with from three to seven projections is adequate to produce a pseudo 3-D geometry that is mechanically equivalent to a measured hip. FIG. 9D is a sequence of seven images depicting a cone-beam reconstruction used to construct a 3-D model according to steps of the method in FIG. 7". The measured hip can be understood to be the generic model and the computed model can be understood to be the actual model or vice versa. Also, Fig. 8: 810; paras 148-150)**.

Mitton teaches (e1) identifying, on at least the first image, predetermined markers corresponding to said osseous body, (e2) determining in the three-dimension reference

system, and by virtue of first means of reconstruction, the geometric position of each marker identified in step (e1) **(Mitton: abstract: "anatomical landmarks visible in more than one projection"; Fig. 1, 3; page 4, col 1; page 3, col 1, para 4: "landmarks were identified by hand")**, and

(e3) determining, by virtue of second means of reconstruction, the three-dimensional shape of an actual model representing said osseous body, by deformation of a predetermined generic model while at the same time keeping markers of this generic model in coincidence, during deformation, with the markers reconstructed by the first means of reconstruction **(Mitton: abstract: "3D reconstruction of additional landmarks that can be identified in only one of the radiographs. The principle of this method is the deformation of an elastic object that respects stereocorresponding and non-stereocorresponding observations available in different projections… The reconstructed geometry obtained is compared with direct measurements using a magnetic digitiser… Comparison results indicate that the obtained reconstruction is close to the actual vertebral geometry. This method can therefore be proposed to obtain the 30 geometry of vertebra"; page 2, col 1, paras 2-3)**.

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to implement the teachings of Mitton into Charles since Charles suggests a system for reconstructing a 3D image/model from multiple 2D radiographic projections using markers in general and Mitton suggests the beneficial use of a system

for reconstructing a 3D image/model from multiple 2D radiographic projections using markers wherein stereoscopic and nonstereoscopic markers are used as to be “an improvement on 3D reconstruction using the DLT procedure. It increases the number of 3D reconstructed points by using 2D points identifiable in only one of the radiographs. The principle of this method is, the deformation of an elastic generic object (deformable mesh) that respects stereocorresponding and nonstereocorresponding observations available in different projection” (Mitton: page 2, col 1, para 2) in the analogous art of image processing. Furthermore, one of ordinary skill in the art at the time the invention was made could have combined the elements as claimed by known methods and, in combination, each component functions the same as it does separately. One of ordinary skill in the art at the time the invention was made would have recognized that the results of the combination would be predictable.

As per claim 10, Charles in view of Mitton teaches Method according to Claim 9, in which the generic model is deformed in such a way that the actual model follows a shape which is as close as possible to an isometry of the generic model **(Charles and Mitton: See arguments made for rejecting claim 9)**.

As per claim 11, Charles in view of Mitton teaches Method according to Claim 9, comprising a step (g) which consists in determining, in a three-dimension reference system, and by virtue of third means of reconstruction, the geometric position of three-dimensional contours belonging to said osseous body, by bringing markers identified in

step (e1) into line with three-dimensional contours of the generic model which are projected onto at least the first image **(Charles: See arguments made for rejecting claim 9)**. Charles does not teach by performing a non- homogeneous geometric deformation of the generic model in order to improve the match between information originating from at least the first image and information representative of the actual model.

Mitton teaches by performing a non-homogeneous geometric deformation of the generic model in order to improve the match between information originating from at least the first image and information representative of the actual model **(Mitton: See arguments made for rejecting claim 9: abstract: "Standard 3D reconstruction of bones using stereoradiograph y is limited by the number of anatomical landmarks visible in more than one projection… deformation of elastic object that respects stereocorresponding and non-stereocorresponding observations available in different projections."; page 2, col 1, para 2: "The method presented in this paper is an improvement on 3D reconstruction using the DLT procedure. It increases the number of 3D reconstructed points by using 2D points identifiable in only one of the radiographs. The principle of this method is, the deformation of an elastic generic object (deformable mesh) that respects stereocorresponding and nonstereocorresponding observations available in different projections")**.

As per claim 12, Charles in view of Mitton teaches Method according to claim 9.

Charles does not teach in which:

during the step (e1), some of the identified markers, called "non-stereo-corresponding control markers", are visible and identified only on a single image,

and, during the step (e2), the geometric position of each non-stereo-corresponding control marker in the three-dimension reference system is estimated from the generic model, by displacing the non-stereo-corresponding control markers of the generic model, each on a straight line joining: on the one hand, the X-ray source to the origin of the image in which a projection of this non-stereo-corresponding control marker is visible and identifiable,

and, on the other hand, the projection of this marker onto this image,

the non-stereo-corresponding control markers thus being displaced to respective positions which minimize the global deformation of the generic model of the object to be observed.

Mitton teaches during the step (e1), some of the identified markers, called "non-stereo-corresponding control markers", are visible and identified only on a single image **(Mitton: abstract: “3D reconstruction of additional landmarks that can be identified in only one of the radiographs”; page 2, col 1, para 3: “by using 2D points identifiable in only one of the radiographs”)**,

and, during the step (e2), the geometric position of each non-stereo-corresponding control marker in the three-dimension reference system is estimated from the generic model, by displacing the non-stereo-corresponding control markers of the generic

model, each on a straight line joining: on the one hand, the X-ray source to the origin of the image in which a projection of this non-stereo-corresponding control marker is visible and identifiable **(Mitton: abstract: "This technique is based on the principle that any non-stereocorresponding point belongs to a line joining the X-ray source and the projection of the point in one view"; abstract: "anatomical landmarks visible in more than one projection"; page 2, col 1, para 7: "joining the X-ray source"; page 3, col 1, para 1: steps 1-4)**,

and, on the other hand, the projection of this marker onto this image **(Mitton: page 2: col 1, para 7 – col 2, para 2)**,

the non-stereo-corresponding control markers thus being displaced to respective positions which minimize the global deformation of the generic model of the object to be observed **(Mitton: page 3, col 1, para 1: step 5; page 3, col 2, paras 2-3)**.

As per claim 13, Charles in view of Mitton teaches Method according to Claim 12. Charles does not teach in which, during the operation (e3), the value of the quadratic sum is minimized:

S = **[Refer to the image file wrapper for amended claim 13 filed 6/20/05]**

where k is a constant coefficient, m is a whole number of imaginary springs joining each marker of the generic model to other markers of this model, k; is a predetermined value of stiffness of the imaginary spring of index i, x10 is the length of the imaginary spring of index i in the initial generic model, and x; is the length of imaginary spring of index i in the generic model during deformation.

Mitton teaches in which, during the operation (e3), the value of the quadratic sum is minimized:

S = **[Refer to the image file wrapper for amended claim 13 filed 6/20/05]**

where k is a constant coefficient, m is a whole number of imaginary springs joining each marker of the generic model to other markers of this model, k; is a predetermined value of stiffness of the imaginary spring of index i, x10 is the length of the imaginary spring of index i in the initial generic model, and x; is the length of imaginary spring of index i in the generic model during deformation **(Mitton: page 2, col 2)**.

As per claim 14, Charles in view of Mitton teaches Method according to claim 9.

Charles does not teach in which:

during the step (e1), at least some of the markers are stereo-corresponding control markers visible and identified on the first image and another image, and, during the step (e3), the geometric position of the stereo-corresponding control markers is directly calculated from measurements of position of the projections of these markers onto the first image and the other image.

Mitton teaches in which:

during the step (e1), at least some of the markers are stereo-corresponding control markers visible and identified on the first image and another image, and, during the step (e3), the geometric position of the stereo-corresponding control markers is directly

calculated from measurements of position of the projections of these markers onto the first image and the other image **(Mitton: See arguments made for rejecting claim 9. abstract: "The principle of this method is the deformation of an elastic object that respects stereocorresponding and non-stereocorresponding observations available in different projections"; page 2, col 1, para 2; page 2, para 5: "The stereocorresponding points that are obWed in at least two different images are reconstructed using the DLT algorithm"; page 3, col 1, para 1-2; page 5, col 2, para 6, Fig. 1)**.

As per claim 16, Charles in view of Mitton teaches Method according to claim 1, in which, during the operation (e), contour lines corresponding to limits of said osseous body and/or to lines of greater grey level density inside these limits are plotted on each image **(Charles: Fig. 9a, 9d. The contours are the edges of the bones)**.

Mitton teaches (e), contour lines corresponding to limits of said osseous body and/or to lines of greater grey level density inside these limits are plotted on each image **(Mitton: Fig. 4)**.

As per claim 23, Charles teaches Device according to Claim 19, in which the calculation means are designed to plot contours or points of the surface of said osseous body on an image of form: Im(x, y) = **[Refer to the image file wrapper for amended claim 23 filed 6/20/05]** where the ai are real coefficients, the fi are functions of R in R, the Si(x,y)

are the absorptiometry values for each pixel (x,y) of said image obtained with a radiation whose energy distribution corresponds to a spectrum i **(Charles: Fig. 4,6-9; para 111; paras 16-19. This can be understood to mean that the pixel values are points that are rendered (plotted) in the bone-surface containing image according to the equation. This can also be interpreted to mean that the bone-surface containing image is created according to the equation, and points pertaining to the bone-surface are plotted. The citations support both interpretations. In considering the equation, not that ai can be assumed to be any value including zero and 1. "i" need not range past one; however the reference refers to multiple individual images pertaining to multiple angles of incidence. "fi" can be arbitrary. Absorptiometry values pertain to x-ray attenuation in tissues. Note that the coordinates (x,y) can be understood to pertain to the pixel locations in the detector array)**.

Mitton teaches the calculation means are designed to plot contours or points of the surface of said osseous body on an image of form: Im(x, y) = **[Refer to the image file wrapper for amended claim 23 filed 6/20/05]** where the ai are real coefficients, the fi are functions of R in R, the Si(x,y) are the absorptiometry values for each pixel (x,y) of said image obtained with a radiation whose energy distribution corresponds to a spectrum i **(Mitton: See arguments made for rejecting claim 9, 11, and 16. abstract: “point-to-surface”; Figs. 1, 3, 4)**.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Atiba Fitzpatrick whose telephone number is (571) 270-5255. The examiner can normally be reached on M-F 10:00am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571)272-7413. The fax phone number for Atiba Fitzpatrick is (571) 270-6255.

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Atiba Fitzpatrick

/A. O. F./

Examiner, Art Unit 2624

/Samir A. Ahmed/
Supervisory Patent Examiner, Art Unit 2624